DEC - 5 2011

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510(K) SUMMARY AS REQUIRED BY SECTION 807.92(C) K111732

Aquamantys SBS 5.0 Sheathed Bipolar Sealer - 510(k) Summary

510(k) owner:	Salient Surgical Technologies, Inc., 180 International Drive, Portsmouth, NH 03801 USA Tel. (603) 294-5446 Fax. (603) 742-1488
Contact Person:	Martin J. Leighton
Date Summary Prepared:	November 23, 2011
Device Trade Name:	Aquamantys SBS 5.0 Sheathed Bipolar Sealer
Common Name:	Electrosurgical Instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Code:	21 CFR §878.4400
Product Code	GEI
Equivalent Device(s):	• Aquamantys 2.3 Bipolar Sealer (K052859) • Aquamantys SS4.0 Bipolar Sealer (K063639) marketed as the Aquamantys Epidural Vein Sealer (EVS)
Device Description:	The Aquamantys SBS 5.0 Sheathed Bipolar Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone and epidural vein sealing at the operative site. Its indications for use include but are not limited to, orthopaedic, spine, endoscopic procedures, abdominal and thoracic surgery, and epidural vein sealing during surgery. The device employs radio-frequency (RF) energy and saline irrigation for hemostatic sealing and coagulation. The effect of RF energy applied to tissues concurrent with a flow of saline results in hemostatic sealing and coagulation of soft tissue and bone without charring; this result has been trademarked "Transcollation® Technology" by Salient Surgical Technologies. The saline helps couple the electrical energy output from the electrosurgical generator to the tissue, increasing the contact area and limiting the surface to a consistent temperature range. (approximately 100 degrees C).

	The vascular system is primarily made up of collagen types I and III. The effect of heat on these fibrous collagens has been well studied. [1, 8] When regularly oriented collagen shrinks along a direction parallel to the dominant direction of fiber orientation, the shrinkage is accompanied by swelling in a direction perpendicular to the fiber orientation. [5, 6] This effectively results in reduction of the vessel lumen diameter and in most cases closure of the vessel lumen. [7-8] References cited follow below. The Aquamantys SBS 5.0 Sheathed Bipolar Sealer is equipped with dual polished stainless steel electrode tips. The electrodes are housed in a two position insulating polymer sheath. The two positions of the sheath are manually established by the surgeon's hand and defined by positive mechanical detents that are detected by the touch. In the sheath open position, the electrodes are fully exposed allowing the surgeon to make use of a majority of their area to contact incised tissue in order to deliver hemostatic sealing and coagulation therapy to broad tissue planes. In the sheath closed position the electrodes are surrounded by the insulating sheath along their length and only exposed at their tips. The closed position allows the surgeon to work adjacent delicate structures while delivering therapy to small areas of incised tissue, or preventing or stopping epidural veins from bleeding. Regardless of sheath position, when the electrodes are activated saline is concurrently delivered from apertures located within the electrode sheath housing. Saline and electrical lines exit the opposite end of the handpiece from the electrodes. The handpiece is equipped with an on-off button that simultaneously activates both RF and saline flow. A saline fluid delivery line is provided with the device, and includes a section of pump tubing and drip chamber with spike. The three-pin electrical connector is designed to be plugged into the Aquamantys Pump Generator.
Intended and Indications for Use:	The Aquamantys SBS 5.0 Sheathed Bipolar Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to orthopaedic, spine, endoscopic procedures, abdominal and thoracic surgery, and epidural vein sealing during surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).
Summary of the technological characteristics of the Aquamantys SBS 5.0 Sheathed Bipolar Sealer device compared to the predicate devices:	In order to establish substantial equivalence of the Aquamantys SBS 5.0 Sheathed Bipolar Sealer to the predicate devices, characteristics including but not limited to the following were assessed and compared. • Intended and indications for use • Construction (including structure and component materials) • Principles of operation and mechanisms of action • Performance of intended and indications for use on live tissues (as conducted per GLP requirements in GLP certified facilities) The results of these comparative assessments found the Aquamantys SBS 5.0 Sheathed Bipolar Sealer substantially equivalent to the equivalent devices (predicates) identified above.
Non-clinical Performance Data:	Performance testing per standardized methods and Salient Surgical's test protocols, including bench testing and *in vivo* animal data collection, was conducted and provides support that the Aquamantys SBS 5.0 Sheathed Bipolar Sealer is substantially equivalent to currently marketed predicate devices. Non-clinical performance test protocols and reports of results are identified in Sections 14 through 19 of this 510(k) submission. Test protocols and reports of results demonstrate that, in consideration of its intended and indications for use, the design, labeling, packaging and sterilization of the Aquamantys SBS 5.0 Sheathed Bipolar Sealer is compliant with the following standards:

	• ANSI/AAMI ISO 11135-1:2007: Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices • ISO 11607-1:2006, Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier • ISO 11607-2:2006: Packaging for terminally sterilized medical devices —Part 2: Validation requirements for forming, sealing and assembly processes, including Annex B (informative) listing of standardized test methods and procedures • ASTM F1980-07; Shelf-life and accelerated aging techniques for standard evaluation of packaging performance • ISO 10993-4:2002, Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood • ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity • ISO 10993-7:2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals • ISO 10993-10:2002 (A1:2006), Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity. • ISO 10993-11:2006, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity • ANSI/AAMI ST72:2002/(R)2010 - Bacterial endotoxins— Test methodologies, routine monitoring, and alternatives to batch testing • AAMI / ANSI ES 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. • IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2: General Requirements For Safety Collateral Standard Electromagnetic Compatibility Requirements And Tests • IEC 60601-2-2:2009, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories
Clinical Performance Data:	Clinical data was not necessary to support that the Aquamantys SBS 5.0 Sheathed Bipolar Sealer is substantially equivalent to currently marketed predicate devices.
Cited References	1. Tanzer ML. Cross-linking of collagen. Science. 1973; 180(86):561-566. 2. Sigel B, Hatke FL. Physical factors in electrocoaplation of blood vessels. Arch Surg. 1967; 95(1):54-58. 3. Gorisch W, Boergen KP. Heat-induced contraction of blood vessels. Lasers Surg Med. 1982; 2(1): 1-13. 4. Miles CA, Bailey Al. Thermally labile domains in the collagen molecule. Micron. 2001; 32(3):325-332. 5. Arnoczky AP, Aksan A. Thermal modification of connective tissues: basic science considerations and clinical implications. JAm Aead Orthop Surg. 2000; 8(5):305-313. 6. Chen SS, Wright NT, Humphrey JD. Heat-induced changes in the mechanics of a collagenous tissue: isothermal, isotonic shrinkage. J Biomech Eng. 1998; 120(3):382-388. 7. Sigel B and Dunn M. The mechanism of blood vessel closure by high frequency electrocoagulation. Sugary, Gynecology & Obstetrics 1965; 821-831. 8. Sigel B, Hatke FL. Physical factors in electrocoaption of blood vessels. Arch Surg 1967; 95: 54-58.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 5 2011

Salient Surgical Technologies, Incorporated
% Mr. Martin Leighton
Director of Regulatory Affairs & Quality Assurance
180 International Drive
Portsmouth, New Hampshire 03801

Re: K111732
Trade/Device Name: Aquamantys SBS 5.0 Sheathed Bipolar Sealer
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 14, 2011
Received: November 17, 2011

Dear Mr. Leighton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

4. INDICATIONS FOR USE STATEMENT

510(k) Number if known: _____

Device Name: Aquamantys SBS 5.0 Sheathed Bipolar Sealer

The Aquamantys SBS 5.0 Sheathed Bipolar Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to orthopaedic, spine, endoscopic procedures, abdominal and thoracic surgery, and epidural vein sealing during surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111732